

0.2 to 3.5 mg/kg for dogs that received a preanesthetic.

(B) *Maintenance of general anesthesia following induction.* Administer an intravenous bolus containing 1.2 to 1.4 mg/kg to provide an additional 6 to 8 minutes of anesthesia in preanesthetized dogs; a dose of 1.5 to 2.2 mg/kg provides an additional 6 to 8 minutes of anesthesia in unpreanesthetized dogs.

(2) *Indications for use.* For the induction and maintenance of anesthesia and for induction of anesthesia followed by maintenance with an inhalant anesthetic, in dogs and cats.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian. Alfaxalone is a Class IV controlled substance.

[77 FR 64717, Oct. 23, 2012, as amended at 79 FR 64116, Oct. 28, 2014]

§ 522.56 Amikacin.

(a) *Specifications.* Each milliliter of solution contains 50 milligrams (mg) of amikacin as amikacin sulfate.

(b) *Sponsor.* See No. 069043 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs—*(1) *Amount.* 5 mg/pound (lb) of body weight twice daily by intramuscular or subcutaneous injection.

(2) *Indications for use.* For treatment of genitourinary tract infections (cystitis) caused by susceptible strains of *Escherichia coli* and *Proteus* spp. and skin and soft tissue infections caused by susceptible strains of *Pseudomonas* spp. and *E. coli*.

(3) *Limitations.* Do not use in horses intended for human consumption. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[76 FR 17338, Mar. 29, 2011, as amended at 78 FR 17597, Mar. 22, 2013; 79 FR 16183, Mar. 25, 2014; 81 FR 17608, Mar. 30, 2016]

§ 522.62 Aminopentamide.

(a) *Specifications.* Each milliliter of solution contains 0.5 milligram (mg) aminopentamide hydrogen sulfate.

(b) *Sponsor.* See No. 054771 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs and cats—*(1) *Amount.* Administer by subcutaneous or intramuscular injection every 8 to 12 hours as follows: For animals weighing up to 10 pounds (lbs): 0.1 mg;

For animals weighing 11 to 20 lbs: 0.2 mg; For animals weighing 21 to 50 lbs: 0.3 mg; For animals weighing 51 to 100 lbs: 0.4 mg; For animals weighing over 100 lbs: 0.5 mg. Dosage may be gradually increased up to a maximum of five times the suggested dosage. Following parenteral use, dosage may be continued by oral administration of tablets.

(2) *Indications for use.* For the treatment of vomiting and/or diarrhea, nausea, acute abdominal visceral spasm, pylorospasm, or hypertrophic gastritis.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[79 FR 16183, Mar. 25, 2014]

§ 522.82 Aminopropazine.

(a) *Specifications.* Each milliliter of solution contains aminopropazine fumarate equivalent to 25 milligrams (mg) aminopropazine base.

(b) *Sponsor.* See No. 000061 in § 510.600(c) of this chapter.

(c) *Conditions of use—*(1) *Dogs and cats—*(i) *Amount.* 1 to 2 mg per pound of body weight, repeated every 12 hours as indicated, by intramuscular or intravenous injection.

(ii) *Indications for use.* For reducing excessive smooth muscle contractions, such as occur in urethral spasms associated with urolithiasis.

(iii) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) *Horses—*(i) *Amount.* Administer 0.25 mg per pound of body weight, repeated every 12 hours as indicated, by intramuscular or intravenous injection.

(ii) *Indications for use.* For reducing excessive smooth muscle contractions, such as occur in colic spasms.

(iii) *Limitations.* Do not use in horses intended for human consumption. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[79 FR 16183, Mar. 25, 2014]

§ 522.84 Beta-aminopropionitrile.

(a) *Specifications.* The drug is a sterile powder. Each milliliter of constituted solution contains 0.7 milligrams (mg) beta-aminopropionitrile fumarate.

(b) *Sponsor.* See No. 064146 in § 510.600(c) of this chapter.

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(c) *Conditions of use in horses*—(1) *Amount.* Administer 7 mg by intralesional injection every other day for five treatments beginning about 30 days after initial injury.

(2) *Indications for use in horses.* For treatment of tendinitis of the superficial digital flexor tendon (SDFT) in horses where there is sonographic evidence of fiber tearing.

(3) *Limitations.* Do not use in horses intended for human consumption. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[79 FR 16183, Mar. 25, 2014]

§ 522.88 Amoxicillin.

(a) *Specifications*—(1) Each vial contains 3 grams (g) of amoxicillin trihydrate. Each milliliter of constituted suspension contains 100 or 250 milligrams (mg) amoxicillin trihydrate for use as in paragraph (d)(1) of this section.

(2) Each vial contains 25 g of amoxicillin trihydrate. Each milliliter of constituted suspension contains 250 mg amoxicillin trihydrate for use as in paragraph (d)(2) of this section.

(b) *Sponsor.* See No. 054771 in § 510.600(c) of this chapter.

(c) *Related tolerance.* See § 556.38 of this chapter.

(d) *Conditions of use*—(1) *Dogs and cats*—(i) *Amount.* Administer 5 mg per pound of body weight daily for up to 5 days by intramuscular or subcutaneous injection.

(ii) *Indications for use*—(A) *Dogs.* For treatment of infections caused by susceptible strains of organisms as follows: Respiratory infections (tonsillitis, tracheobronchitis) due to *Staphylococcus aureus*, *Streptococcus* spp., *Escherichia coli*, and *Proteus mirabilis*; genitourinary infections (cystitis) due to *S. aureus*, *Streptococcus* spp., *E. coli*, and *P. mirabilis*; gastrointestinal infections (bacterial gastroenteritis) due to *S. aureus*, *Streptococcus* spp., *E. coli*, and *P. mirabilis*; bacterial dermatitis due to *S. aureus*, *Streptococcus* spp., and *P. mirabilis*; soft tissue infections (abscesses, lacerations, and wounds), due to *S. aureus*, *Streptococcus* spp., *E. coli*, and *P. mirabilis*.

(B) *Cats.* For treatment of infections caused by susceptible strains of organisms as follows: Upper respiratory in-

fections due to *S. aureus*, *Staphylococcus* spp., *Streptococcus* spp., *Haemophilus* spp., *E. coli*, *Pasteurella* spp., and *P. mirabilis*; genitourinary infections (cystitis) due to *S. aureus*, *Streptococcus* spp., *E. coli*, *P. mirabilis*, and *Corynebacterium* spp.; gastrointestinal infections due to *E. coli*, *Proteus* spp., *Staphylococcus* spp., and *Streptococcus* spp.; skin and soft tissue infections (abscesses, lacerations, and wounds) due to *S. aureus*, *Staphylococcus* spp., *Streptococcus* spp., *E. coli*, and *Pasteurella multocida*.

(iii) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) *Cattle*—(i) *Amount.* Administer 3 to 5 mg per pound of body weight daily for up to 5 days by intramuscular or subcutaneous injection.

(ii) *Indications for use.* For treatment of diseases due to amoxicillin-susceptible organisms as follows: Respiratory tract infections (shipping fever, pneumonia) due to *P. multocida*, *P. hemolytica*, *Haemophilus* spp., *Staphylococcus* spp., and *Streptococcus* spp. and acute necrotic pododermatitis (foot rot) due to *Fusobacterium necrophorum*.

(iii) *Limitations.* Treated animals must not be slaughtered for food during treatment and for 25 days after the last treatment. Milk from treated cows must not be used for human consumption during treatment or for 96 hours (8 milkings) after last treatment. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[79 FR 16183, Mar. 25, 2014]

§ 522.90 Ampicillin injectable dosage forms.

[79 FR 16183, Mar. 25, 2014]

§ 522.90a Ampicillin trihydrate suspension.

(a) *Specifications.* (1) Each milliliter contains ampicillin trihydrate equivalent to 200 milligrams (mg) of ampicillin.

(2) Each milliliter contains ampicillin trihydrate equivalent to 150 mg of ampicillin.

(b) *Sponsors.* See sponsor numbers in § 510.600(c) of this chapter.